

K050956

FEB 16 2006

510(k) Summary

Submitter: Sudimplant, SA
Parc de la Plaine
24, impasse René Couzinet
31500 Toulouse, FRANCE
Tel: +335 62 16 71 00
Fax: +335 61 80 84 02

Contact: Mr. Didier Sailhan
Regulatory Affairs Manager
E-mail: production@tbridea.com

Date: June 22, 2005

Device Name: T.B.R.® ide@ conic

Classification Name: Endosseous dental implant (21 CFR 872.3640) and Endosseous dental implant abutment (21 CFR 872.3630)

Legally marketed device (predicate devices):

- 3i Osseotite Certain NT (K031475)
- Bio-Lok Silhouette & Silhouette IC (K032454)
- Zimmer Dental (formerly Sulzer Dental) Tapered Screw-Vent (K013227, K011028)

Description of the device:

The T.B.R.® ide@ conic/Conic dental implant system consists of self-tapping threaded screw-type implants (made from Ti-6Al-4V) and restorative components with many options such as Ti-6Al-4V abutments, tapered abutments, castable abutments, ball abutments and ceramic/Ti-6Al-4V abutments. The system also include surgical and laboratory accessories. Implants are double-packaged and provided sterile. Implants surface is roughened to promote osseointegration.

Intended use:

The T.B.R.® ide@ conic endosseous dental implant is a device intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as artificial teeth, and to restore the patient's chewing function.

Summary of testing:

Mechanical testing was done in accordance with the FDA guidance "Class II Special controls guidance document: Root-form endosseous dental implants and endosseous dental abutments" issued on May 12, 2004. Results from an independent laboratory showed T.B.R.® ide@ conic to have sufficient mechanical static and dynamic strength. Additionnal test

report include biocompatibility testing. Test conclusions demonstrate the safety and effectiveness of T.B.R.® ide@ conic implant system.

Technological characteristics:

The overall design and characteristics of the T.B.R.® ide@ conic/Conic implants are similar to the predicated devices and as safe, as effective and as performs as well or better than the legally predicate devices.

	New device	Predicate Devices		
	Conic	Bio-Lok Silhouette	Zimmer Tapered Screw-Vent	3i Osseotite Certain NT
510(k) number		K032454	K013227 K011028	K031475
Type	Self-Tapping Threaded Screw	Self-Tapping Threaded Screw	Self-Tapping Threaded Screw	Self-Tapping Threaded Screw
Lengths (mm)	8-15,5	8-15	8-16	8,5-15
Diameters (mm)	3,5-5	3,45-6,5	3,5-5,7	3,25-6
Connection	Internal Octagon	Internal Connection or External hexagon	Internal Hexagon	Internal Hexagon
Shape	Tapered	Tapered	Tapered	Tapered
Materials	Ti-6Al-4V	Ti-6Al-4V	Ti-6Al-4V	Ti-6Al-4V
Surface	Sandblasted/ Acid-etched	Osseo-Lok HA-coated Laser-Lok	Machined / blasted- etched Machined/HA	Acid-etched
Sterility	Gamma	Unknown	Unknown	Gamma
Abutment containing ceramic	Available	Available	No	No



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

FEB 16 2006

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Didier Sailhan
Regulatory Affairs Manager
Sudimplant SA
24 Impasse Rene Couzinet
Parc De La Plaine
Toulouse, France 31500

Re: K050956
Trade/Device Name: T.B.R.[®] ide@-conic
Regulation Number: 872.3640
Regulation Name: Endosseous dental implant
Regulatory Class: II
Product Code: DZE
Dated: January 20, 2006
Received: January 20, 2006

Dear Ms. Sailhan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.


If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Chiu Lin, Ph.D.", written in a cursive style.

Chiu Lin, Ph.D.

Director

Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K050956

Indications for Use

510(k) Number (if known):

Device Name: T.B.R.® ide@ conic

Indications For Use:

The T.B.R.® ide@ conic endosseous dental implant is a device intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as artificial teeth, and to restore the patient's chewing function.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

Sharon R. Roes

Chief of Hospital

Medical Services

K050956